UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2342-1
Program	Prior Authorization/Medical Necessity
Medication	Tryvio™ (aprocitentan)
P&T Approval Date	6/2024
Effective Date	9/1/2024

1. Background:

Tryvio (aprocitentan) is an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Resistant hypertension (RH) is defined as above-goal elevated blood pressure (BP) in a patient despite the concurrent use of 3 antihypertensive drug classes, commonly including a long-acting calcium channel blocker, a blocker of the renin-angiotensin system (angiotensin-converting enzyme inhibitor or angiotensin receptor blocker), and a diuretic. The antihypertensive drugs should be administered at maximum or maximally tolerated daily doses.[1]

Tryvio is only available through a restricted distribution program called the Tryvio REMS.

2. Coverage Criteria[a]:

A. Initial Authorization

1. Tryvio will be approved based on **all** of the following criteria:

   a. Diagnosis of resistant hypertension

   -AND-

   b. One of the following:

      1) Systolic blood pressure ≥ 130 mm Hg on two consecutive measurements

      -OR-

      2) Diastolic blood pressure ≥ 80 mm Hg on two consecutive measurements

   -AND-

   c. Patient is on a stabilized dose and receiving concomitant therapy with **all** of the following:

      1) Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]
      2) Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)
      3) Maximally tolerated diuretics (e.g., hydrochlorothiazide)

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-AND-

d. **One** of the following:

1) Patient is on a stabilized dose and receiving concomitant therapy with a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

-OR-

2) Patient has a contraindication, or intolerance to mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)]

-AND-

e. **One** of the following:

1) Patient is on a stabilized dose and receiving concomitant therapy with a beta-blocker (e.g., labetalol, carvedilol)

-OR-

2) Patient has a contraindication, or intolerance to beta-blockers (e.g., labetalol, carvedilol)

-AND-

f. Prescribed by or in consultation with a cardiologist

Authorization will be issued for 12 months

B. Reauthorization

1. **Tryvio** will be approved based on **both** of the following criteria:

a. Documentation the patient is receiving clinical benefit to Tryvio therapy

-AND-

b. Patient is on a stabilized dose and receiving concomitant therapy with **all** of the following:

1) Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]
2) Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)
3) Maximally tolerated diuretics (e.g., hydrochlorothiazide)

Authorization will be issued for 12 months

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[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Tryvio [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc; March 2024.
2. Carey, RM, Calhoun, DA, Bakris, GL, et. al. Resistant Hypertension: Detection, Evaluation, and Management: A Scientific Statement From the American Heart Association. *Hypertension*. 2018: 72(5); e53-e90.

Program	Prior Authorization/Medical Necessity - Tryvio
Change Control	
Date	Change
6/2024	New program.

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